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August 13, 2008

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Dr. Laura Tarantino, Director
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Re: GRAS Notification for Grain Millers, Inc.'s Oat Fiber

Dear Dr. Tarantino:

Pursuant to the regulatory and scientific procedures established in proposed 21 C.F.R. § 170.36, Grain Millers, Inc. has determined that its Oat Fiber, an insoluble fiber processed from oat hulls, is a Generally Recognized as Safe ("GRAS") substance for its intended use and is, therefore, exempt from the requirement for premarket approval.

We are hereby submitting, in triplicate, a GRAS notification, in accordance with proposed 21 C.F.R. § 170.36, informing FDA of the view of Grain Millers, Inc. that the Oat Fiber is GRAS through scientific procedures for use as an ingredient in food systems as a source of dietary fiber and at levels consistent with current Good Manufacturing Practices (cGMP).

If you have questions or require additional information, please contact me at (202) 778-9124.

Sincerely Yours,

Gary L. Yingling

Enclosures

DC-1198278 v6

GRAS Notification
Oat Fiber

Grain Millers, Inc.
315 Madison Street
Eugene, OR 97402

August 13, 2008

GRAS Notification for Oat Fiber

1. General Introduction

Grain Millers, Inc.'s Oat Fiber is processed from oat hulls by a proprietary hydrothermal process in the absence of chemical processing aids. Oat Fiber is an insoluble fiber that is added to food for several purposes, including, but not limited to, raising total dietary fiber, reducing caloric content, controlling water activity, and modifying the rheological properties of food systems.

Pursuant to the regulatory and scientific procedures established by proposed regulation 21 C.F.R. § 170.36, Grain Millers, Inc. has determined that its Oat Fiber is a GRAS substance for the intended use in foods and is therefore exempt from premarket approval requirements of the Federal Food, Drug, and Cosmetic Act (FDCA). The chemical composition of oat hull fiber is substantively the same as other oat fiber tissues configuring the oat kernel, cell wall materials, i.e., celluloses and hemicelluloses, in particular. In addition, Oat Fiber enjoys a long history of safe consumption. More recently, it has risen in popularity as a highly desirable food ingredient in several final finished food products (e.g., Oat Fiber enriched bakery goods, Ready-to-Eat ("RTE") cereals, energy bars, reduced and low calorie meal-replacement products, etc.). In addition, Health Canada has classified oat hull fiber as a novel fiber source that is acceptable for use in grain and bakery products. See Attachment 1.

General information identifying the Oat Fiber final product, its applicable conditions for use, Grain Miller's basis for its GRAS determination and the availability of supporting information and reference materials for FDA's review can be found in Section 1. Information on the safety of the raw materials and manufacturing process for the Oat Fiber providing the basis for this GRAS determination is described in Section 2. Information regarding the product characteristics and specifications of the final finished Oat Fiber is presented in Section 3. A discussion of the intended use and functional properties of the ingredient in foods is presented in Section 4, and the safety of the ingredient, including an executive summary of clinical results confirming the Oat Fiber's safety, is discussed in Section 5.

1.1 Name and Address of Notifier

Grain Millers, Inc.
315 Madison Street
Eugene, OR 97402

1.2 Common or Usual Name of Substance

Oat Fiber

1.3 Applicable Conditions of Use

Oat Fiber is intended for the addition to food at levels consistent with current Good Manufacturing Practices (cGMP) and is self-limiting for technological reasons. Such technological reasons may include taste, color and rheological impacts. And although Grain Millers' clinical trials were successfully completed with no adverse events at a level of incorporation of seven (7) grams per fifty (50) gram serving, we estimate that in most food applications, oat fiber is formulated to provide a dietary fiber range of between 2.5-5.0 grams per serving.

1.4 Basis for GRAS Determination

Grain Millers Inc. has determined that Oat Fiber is GRAS for use as an ingredient in foods on the basis of scientific procedures.

1.5 Availability of Information for FDA Review

The data and information that are the basis for Grain Millers' GRAS determination are available for the Food and Drug Administration's (FDA) review and copying at reasonable times at the offices of Grain Millers, Inc., 315 Madison St., Eugene, OR 97402 or will be sent to FDA upon request.

2. Manufacturing Process

2.1 Raw materials

The origin of the fiber source consists of pre-qualified, cleaned oat hulls. The pre-qualification consists of pre-selection of the oat hull for color, odor, moisture content, multiple residue analysis (MRA not to exceed Food Chemical Codex's maximum levels for human consumption), mycotoxins (not to exceed USDA's and FDA's maximum threshold), and heavy metals (not to exceed Food Chemical Codex's maximum levels for arsenic, cadmium, mercury, chromium and lead).

2.2 Manufacturing Process

Pre-qualified oat hulls (see 2.1 above) are cleaned through mechanical detachers, gravity separators, sieves and air classifiers to render the oat hulls free from oat groat fragments and any residual content of trichomes. Subsequently, the pre-cleaned oat hulls are exposed to heat and shear conditions with specified moisture content for specific time periods. Immediately thereafter, the treated oat hulls are reduced in particle size.

The pre-qualified oat hulls are reduced to a powder form characterized by the following particle size distribution using Jet Sieve analyses:

Screen (mesh size)	(%)
> 100	0.5 max.
< 100 > 200	3.0 +/- 1.0
< 200 > 270	5.0 +/- 1.0
< 270 > 400	8.0 +/- 0.5
PAN	85.0 +/- 1.0

The treatment described above breaks down the crystalline nature of the cell walls into a more texturally palatable fiber and increases the water absorption of raw ground oat fiber, depending on treatment conditions.

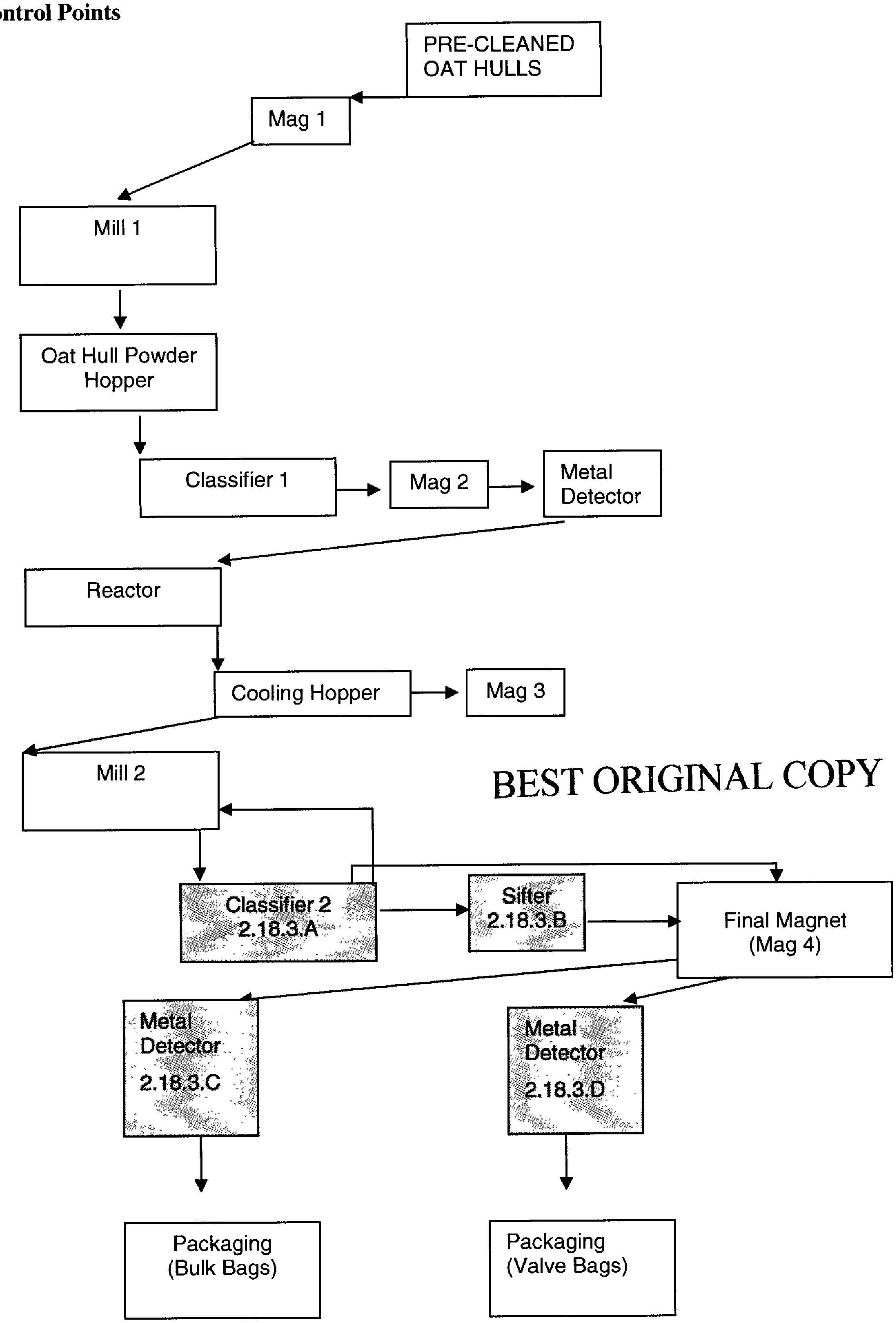
2.3 Quality Control of Manufacturing Process

Grain Millers, Inc. manufactures the Oat Fiber with its AIB-inspected, HACCP-designed manufacturing process. In addition to the HACCP-designed manufacturing process, Grain Millers, Inc. employs a plant sanitation program, pest control program, chemical control program (to ensure chemical usage in the plant for pest control, sanitation, maintenance, and laboratory use meets OSHA regulations), allergen control program (to identify, segregate, and control allergens), preventative maintenance program (to routinely maintain equipment), product recall program, customer complaint program.

Below is a flow-diagram of the HACCP plan for manufacturing the Oat Fiber.

Flow Chart HACCP FLOW DIAGRAM: Oat Fiber

= Critical Control Points



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3. Product Characteristics and Specifications

The ingredient that is the subject of this GRAS notification is a processed oat fiber. It has an insoluble dietary fiber content of approximately 89%, a mean particle size of 43 microns, and a water holding capacity of 318%.

3.1 General Physical Properties

Color: Cream to natural oatmeal
Flavor: Bland to slightly sweet, no off flavors
Physical form: Fine powder
Odor: Natural clean cereal, no off odors
Hydratability (water absorption in mls/g by centrifugation): 3.0 +/- 0.3

Particle Size Distribution:	Sieve Size	(%)
	> 100	0.5 max.
	< 100 > 200	3.0 +/- 1.0
	< 200 > 270	5.0 +/- 1.0
	< 270 > 400	8.0 +/- 0.5
	PAN	85.0 +/- 1.0

3.2 Physical/Chemical Specifications

Test	Target	Units	Method
Bulk Density	14.5	lbs./cu. ft.	GME B.1
Granulation, US #100 0	5.0 max	%	GME B.3.6
Absorption	300	%, db	GME B.6.5
Moisture	3.0	%	AACC 44-15A
Protein	3.0	%, as is	AACC 46-30
Fat	1.0	%, as is	AACC 30-20
Fat acidity	<0.5	%, as oleic acid	AACC 02-02A
Total Dietary Fiber	85.0	%, as is	AACC 32-05
Insoluble Fiber	84.5		
Soluble Fiber	0.5		
Enzyme Activity		Pass / Fail	GME C.2
Ash	5.0	%, as is	AACC 08-02
pH	5.5-7.0		AACC 02-52

3.3 Microbiological Specifications

	Reference Method
Standard Plate Count....<5 x 10^3 (cfu[1]/g)	FDA-BAM[2] Chap. 3
S. Aureus..................Negative (prescence/25g)	FDA-BAM[2] Chap. 4
E. Coli.....................Negative (prescence/25g)	FDA-BAM[2] Chap. 4
Salmonella................Negative (presence/25g)	FDA-BAM[2] Chap. 5
Yeast and Mold...........<200/gm	FDA-BAM[2] Chap. 19

1 Cfu = Colony forming units
2 BAM = Bacteriological Analytical Manual On-line, January 2001

3.4 Nutrition Content

Nutrient content per 100 g	Typical
Calories (kcal)	370.6
Total Fat (g)	0.6
Saturated fat (g)	.1
Monounsaturated fat (g)	0.2
Polyunsaturated fat (g)	0.2
Trans fat (g)	0
Cholesterol (mg)	0
Total carbohydrates (g)	88.5
Sugars (g)	0
Total dietary fiber (g)	86.3
Ash (g)	5.3
Protein (g)	2.8
Sodium (mg)	15
Potassium (mg)	470
Vitamin A (IU)	0
Vitamin C (mg)	0
Calcium (mg)	63.5
Iron (mg)	2.8
Magnesium (mg)	61

Data were calculated based on chemical analysis and is reported for those nutrients that are mandatory on the nutrition information panel. Data on calories were derived using 4 calories per g for carbohydrates and protein, and 9 calories per g for fat.[1] Insoluble fiber g was subtracted from total carbohydrate g to determine calories (total). These calculations were completed consistent with 21 C.F.R. § 101.9(c)(1)(i)(C). For further information see the USDA website for nutritional data at: www.nal.usda.gov/fnic/foodcomp.

4. Application

The Oat Fiber's appealing textural characteristics and pleasant cereal flavor together with a high level of Total Dietary Fiber (values > 85%) offer numerous food applications. Such applications include, but are not limited to, raising total dietary fiber, reducing caloric content, controlling water activity and modifying the rheological properties of food systems. The most compatible food systems include bakery, cereal, snack, meat and spice systems.

4.1 Examples of Potential Applications of Oat Fiber in Processed Foods

- Formulating food products to become excellent sources of dietary fiber by incorporating oat fiber containing more than 80% total daily fiber.

[1] Derived from Atwater Method: 2.8 g protein x 4 + 0.6 g fat x 9 + 88.5 g carbohydrate x 4 = 370.6 k calories.

- Water activity controller, i.e., binding water approximately three times its weight.
- Dough yield improvers by absorbing water three times its weight.
- Crumb humectant in high moisture (>30% moisture content) baked goods, i.e., breads, buns, etc. by absorbing and retaining water during the baking process.
- Friability index improver in low moisture (< 5% moisture content) baked products, i.e. variety crackers, RTE cereals and fried snacks such as corn chips.
- Reduced calorie baked goods formulation by recognizing a 0 Kcal/g of oat fiber containing a minimum Total Dietary Fiber of 85%.

4.2 Use Levels

Levels of use will depend on product target design but it would typically range from 2-5 grams per serving with the high end looking to reduce carbohydrates and the low end to qualify products as good sources of dietary fiber.

5. Safety Evaluation

5.1 Safety of Oat Fiber

5.1.1 Long History of Safe Use

Oats are a hardy cereal grain used to produce various types of oat products, which are generally used to make breakfast cereals, baked goods, and stuffings. Oats have been cultivated for two thousand years in various regions around the world. Historically, the growing of oats in Europe was widespread, and oats constituted an important commercial crop since they were a dietary staple for the people of many countries, including Scotland, Great Britain, Germany, and the Scandinavian countries. Today, leading oat-producing countries include the United States, Belarus, Russia, Kazakhstan, Canada, France, Poland, Finland, Germany, and Australia.[2]

Although oats are used chiefly as livestock feed, some are processed for human consumption, especially as breakfast foods. Rolled oats, flattened kernels with the hulls removed, are used mostly for oatmeal; other breakfast foods are made from the groats, kernels with husks removed, but unflattened. Oat flour is

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[2] Encyclopedia Britannica, Oats, *available at* http://www.britannica.com/EBchecked/topic/423545/oats.

used to make cookies and puddings. Oat grains are high in carbohydrates and contain about 13 percent protein and 7.5 percent fat. They are a source of calcium, iron, vitamin B_1, and nicotinic acid.[3]

Oat hulls contain a high level of insoluble fiber in the form of cellulose and hemicelluloses and were not traditionally used for food applications primarily because of its crystalline texture. Grain Millers, Inc. manufacturing process increases the permeability of oat hulls, rendering them a texturally acceptable and palatable Oat Fiber. The Oat Fiber contains no sulfites, added flavors, components from an animal source, BHA, BHT, genetically altered plant material, nor irradiated material. Only vitamin E is added to the Oat Fiber to maintain freshness.

The U.S. Department of Health and Human Services (HHS) and USDA, in its Dietary Guidelines for Americans, recommend that all adults eat half their grains as whole grains, which includes oats and whole wheat.[4] USDA and HHS recommend the daily intake of dietary fiber to be 14 grams per 1000 calories,[5] which is 20-35 grams per day.

There are numerous scientific articles studying the health effects of insoluble oat fiber when consumed. See Section 5.4 below. There are no reports of safety concerns in any of the studies that were reviewed. There are also numerous publications on the use of oat hull fiber in food.[6] Further, a number of over-the-counter, retail products with a long and successful track-record of use including but not limited to such well recognized laxative brands as Metamucil, together with popular bakery goods, i.e. low-calorie-

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[3] Encyclopedia Britannica, Oats, *available at* http://www.britannica.com/EBchecked/topic/423545/oats.

[4] HHS/USDA Dietary Guidelines for Americans, 2005 p. 25, 28 (Table 7), *available at* http://www.health.gov/dietaryguidelines/dga2005/document/pdf/DGA2005.pdf (last visited June 4, 2008).

[5] HHS/USDA Dietary Guidelines for Americans, 2005, *available at* http://www.health.gov/dietaryguidelines/dga2005/document/html/chapter7.htm.

[6] See, e.g., Galdeano, MC, Grossmann, MVE, Oat Hulls Treated With Alkaline Hydrogen Peroxide Associated with Extrusion as Fiber Source in Cookies, CIENC. TECNOL. ALIMENT., CAMPINAS, 26(1): 123-126 (Jan-March 2006) (discussing the acceptability and feasibility of using oat hull fiber in cookies); Fernandez-Garcia, E, McGregor, JU, Traylor, S, The Addition of Oat Fiber and Natural Alternative Sweeteners in the Manufacture of Plain Yogurt, J. Dairy Sci. 81:655-663 (1998) (discussing the acceptability and feasibility of adding oat fiber to yogurt). *See* Attachments 2 and 3 respectively.

high-fiber breads, attest t o safety and beneficial health effects of insoluble oat fiber consumption.

5.1.2 Allergenicity

There are trace amounts of wheat in the product, and Grain Millers, Inc. recommends its customers declare on final finished products the potential presence of wheat as an allergen.

5.2 Quality Control of the Manufacturing Process

As described in Section 2.2, aside from the hydrothermal treatment of the oat hull, Grain Millers, Inc. uses a manufacturing process similar to that used for other grains. In order to control the manufacturing process, as described in Section 2.3 of this Notification, Grain Millers, Inc. operates a self-audited HACCP program along with several other Programs in order to manufacture high quality and pure product. With several critical control points, Grain Millers, Inc. ensures that the manufacturing process minimizes the introduction of impure or unsafe materials to the finished product.

Grain Miller's manufacturing system is audited by third parties on a regular basis, for example the American Institute of Baking (or AIB International) and the Food Products Association (FPA) (formerly the National Food Processors Association or NFPA). In addition, Grain Millers' Oat Fiber is Oregon Tilth Certified Organic. The Oat Fiber is also certified as Kosher by the Orthodox Union (OU), Pareve Status.

5.3 Quality Control of the Finished Product

Grain Millers, Inc. tests its final product and issues corresponding certificates of analysis to ensure quality and adherence to the product specifications enumerated in Section 3 of this Notification. In addition, the company tests production batches using standardized test methods as referenced below:

<u>Microbiological Analysis</u>

	Typical	**Reference Method**
Aerobic Plate Count	<50,000 Cfu/g[1]	FDA-BAM Chapter 3
Coliform	< 100 Cfu/g	FDA-BAM Chapter 4
E. coli	<10 Cfu/g	FDA-BAM Chapter 4
Salmonella	Negative/25 g	AOAC 989.14
Yeast	<1,000 Cfu/g	FDA-BAM Chapter 18
Mold	<1,000 Cfu/g	FDA-BAM Chapter 18

1 Cfu = Colony forming units
2 BAM = Bacteriological Analytical Manual On-line, January 2001

Chemical Analysis

Mycotoxins:	Method Reference
DEOXYNIVALENOL (DON or VOMITOXIN) = 0.1 +/- 0.1 PPM	USDA/GIPSA #2007-005
AFLATOXIN = < 10 PPB	AOAC Official Method 990.32 USDA/GIPSA #2006-09

Heavy Metals	
ARSENIC	ND
CADMIUM	ND
MERCURY	ND
CHROMIUM	0.17+/-0.1
LEAD	0.08+/-0.03

Key: ND = None Detected
Metals Method Reporting Limit (MRL) in mg/kg (ppm) at a level of detection As – 0.07, Cd, Cr, Pb, Hg – 0.05

5.4 Safety Studies

Insoluble oat fiber originates primarily from oat hulls, which are part of the whole oat grain, and oat grain's safety is well-established based on its use as a food. There are abundant literature references describing the composition of the oat kernel and its parts, including the bran layers and the hulls.[7] The difference between the bran layers and the oat hulls resides primarily in the occurrence of different tissue components that, in turn, create textural variability, i.e., inflexible versus flexible configurations of the non-starchy polysaccharides. This is particularly true of certain tissues, e.g., strands of celluloses, hemicelluloses and pentosans (xylans in particular) that are unevenly distributed throughout the whole kernel, including the oat groat (dehulled oat), which is traditionally recognized as the palatable "edible" portion of the whole oat.

Because the basic safety of oat fiber from oat hulls is not in question, there are none of the basic toxicity studies on rats or other species that one would expect to exist in the scientific literature. In their place are a number of human and animal studies that examine the effect of oat hull fiber on the human or animal. As part of the study, adverse events are recorded.

[7] Marlett, J.A., 1993. Oat Bran. Comparisons of Dietary Fiber and Selected Nutrient Compositions of Oat and Other Grain Fractions. American Association of Cereal Chemists, Inc. St. Paul, MN.

There is a human study on the effects of oat hull fiber on human colonic function and serum lipids published in 1997. See Stephen, AM, et al., Effect of Oat Hull Fiber on Human Colonic Function and Serum Lipids, CEREAL CHEM., 74(4):379-383 (1997) (Attachment 4). This controlled study examined the effect of oat hull fiber on colonic function and serum lipids on 10 healthy males, aged 20-37, who ate, for two 3-week periods, a controlled low fiber diet (13.1 g of nonstarch polysaccharide (NSP)/day), and the same diet with 25g of oat hull fiber per day incorporated into foods, providing 17 g of NSP/day. Id at 379. Fermentation of oat hull fiber was studied by an analysis of feces for NSP. The study indicated that no degradation of the oat hull fiber occurs and passes through to the feces intact. Oat hull fiber is therefore resistant to fermentation in the human colon. Any possible contribution of short-chain fatty acids to overall energy supply or to other processes cannot occur with oat hull fiber because no fermentation takes place. An effect on serum cholesterol would therefore not be expected, and none occurred. Therefore, oat hull fiber has no effect on serum lipids and provides no energy to the body. Id at 383. No subjects reported any adverse gastrointestinal effects of eating oat hull fiber. Id at 381.

Grain Millers, Inc. completed a study in April 2008, entitled, Safety and Laxative Efficacy of Oat Hull Fiber (Attachment 5). This controlled, randomized, partially blind,[8] crossover study assessed the safety and physiological effect (laxation and glycemic response) of Grain Miller's oat hull fiber. This study examined 12 females[9] and 8 males, aged 22-61 years old (average 41.25 years) and lasted for 21 weeks. The study used basic white bread with added oat hull fiber and basic cornflake cereal with added oat hull fiber as the test foods. The test foods were compared against a negative control diet (fiber-unsupplemented cornflakes and fiber-unsupplemented white bread, i.e., each of the two negative controls were in the same treatment period); and a positive control diet (AACC wheat bran supplemented cornflakes and AACC wheat bran supplemented white bread[10]). All the fiber-supplemented diets (AAC wheat bran or oat hull

[8] The study notes that it was difficult to maintain complete blinding as the control foods and the test foods were quite different in appearance from each other. However, "subjects could not determine which of the "non-white" breads was the oat hull fiber bread and which was un-supplemented bread. Similarly, both the plain cereal and the oat hull cereal appeared very similar, so subjects were unable to differentiate them, and the trial coordinator was equally unaware." Moreover, "the subjects were not cognizant of which fiber was the test fiber." The study concludes that there was partial blinding of the study.

[9] One subject has minimal stool output on all diets and, although she consumed a capsule at the start of every stool collection period, no "rings" were ever observed in her stools to measure transit time for the fiber source. Her data was omitted from the data analysis.

[10] The positive control diet for the cereal test food consisted of 50 g wheat bran cornflakes and one 60g slice of white bread. The positive control diet for the bread test food consisted of 5 g unsupplemented cornflakes and one 60g slide of AACC wheat bran supplemented white bread.

fiber) were formulated to add a further 6-7g fiber to a 50g portion of cereal or a 60g slice of white bread. Study subjects were also instructed to consume a gelatin capsule every 4 weeks, prior to the stool sampling, to enable the researchers to measure transit time.

Study subjects were instructed to record any adverse events. Adverse events were minor and consisted of gas, cramps, sore/upset stomach, problems with bowel movements, bloating, headache, heartburn, loose stools/diarrhea. There was no pattern of adverse events on any particular diet, and none of the symptoms lasted more than a day or two.

The study was completed with no subjects dropping out or presenting any adverse events at dosage levels of seven (7) grams fiber per fifty (50) gram servings, for a total recommended daily dosage of twenty (20) grams of fiber. The study concludes, "The results indicate that [oat hull fiber] is safe to consume as a source of dietary fiber and has a laxative effect equal to or greater than AACC wheat bran."

Finally, there is a study on the therapeutic benefit of insoluble oat fiber on a human disease condition. See, e.g., Weickert, MO, et al., Cereal Fiber Improves Whole-Body Insulin Sensitivity in Overweight and Obese Women, Diabetes Care Vol 29, Num 4, 775-780 (April 2006) (concluding that increased insoluble dietary fiber intake for 3 days significantly improved whole-body insulin sensitivity, suggesting a potential mechanism linking cereal fiber intake and reduced risk of type 2 diabetes) (Attachment 6).

In addition to this human study, the effects of feeding oat hull fiber to animals have been studied in pigs (Moser et al., 1982, Moore et al., 1986), rats (Barke and Harrold, 1980), chicks (Thompson and Weber 1981), and cattle (Smith et al., 1980). While the studies focused on the effect, no adverse events related to the consumption of oat hull fiber were reported in any of these animal studies.[11] These studies indicate that the consumption of oat hull fiber by these animals is safe.

In all these studies, there was no discussion on adverse effects or safety risks in consuming the insoluble oat hull fiber. This scientific data supports a conclusion that the feeding of oat hull fiber is safe.

5.5 Estimates of Human Consumption and Safety Margin

Grain Millers, Inc. anticipates that the average consumer will consume Oat Fiber in some, but not all, of their daily fiber-based food selections. Grain

[11] In the Smith study comparing oat hulls to maize starch as energy supplements, one yearling heifer became chronically lame. There is no indication that this condition was related to the consumption of oat hull fiber.

Millers, Inc. estimates that its Oat Fiber will be consumed at a rate of between 2-5 grams per 50 gram serving for a total daily consumption of 21-28 grams. This estimate is based on levels of consumption that comply with dietary fiber source claims (e.g., high source and very high source) which are considered safe as little to no adverse effects have been observed or reported. This consumption estimate is based on the potential use of oat fiber in the various foods (e.g., baked goods, cereals, snacks, meats, spices) listed above.

5.6 Results and Conclusions

Oat Fiber enjoys a long history of use in foods in the United States. Grain Millers, Inc. utilizes a HACCP-controlled manufacturing process and rigorously tests its final production batches to verify adherence to quality control specifications. Grain Millers, Inc. estimates that its Oat Fiber will be consumed at a rate of between 2-5 grams per 50 gram serving for a total daily consumption of 20 grams. The literature/studies demonstrate that Grain Millers' Oat Fiber offers consumers a safe fiber source manufactured under the highest standards of food purity. Therefore, Grain Millers, Inc. has established that its Oat Fiber for use as an ingredient in food is GRAS and, therefore, is exempt from the premarket approval requirements of the FDCA.

6. List of References

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- Smith, T, Broster, WH, and Siviter, JW. 1980. An assessment of barley straw and oat hulls as energy sources for yearling cattle, J. AGRIC. SCI. 95:677-868.

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7. List of Attachments

1) Canadian Food Inspection Agency: Dietary Fibre – Summary of Sources, Acceptability and Labeling Table 6-12.

2) Galdeano, MC, Grossmann, MVE, Oat Hulls Treated With Alkaline Hydrogen Peroxide Associated with Extrusion as Fiber Source in Cookies, CIENC. TECNOL. ALIMENT., CAMPINAS, 26(1): 123-126 (Jan-March 2006).

3) Fernandez-Garcia, E, McGregor, JU, Traylor, S, The Addition of Oat Fiber and Natural Alternative Sweeteners in the Manufacture of Plain Yogurt, J. DAIRY SCI. 81:655-663 (1998).

4) Stephen, AM, et al., Effect of Oat Hull Fiber on Human Colonic Function and Serum Lipids, CEREAL CHEM., 74(4):379-383 (1997).

5) Grain Millers, Inc., Safety and Laxative Efficacy of Oat Hull Fiber (2008).

6) Weickert, MO, Mohlig, M, Schofl, C, Arafat, AM, Otto, B, Viehoff, H, Koebnick, C, Kohl, A, Spranger, J, Pfeiffer, AFH, Cereal Fiber Improves Whole-Body Insulin Sensitivity in Overweight and Obese Women, Diabetes Care Vol. 29, Num 4, 775-780 (April 2006).

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Dietary Fibre - Summary of Sources, Acceptability and Labelling
Table 6-12
(Source: Health Products and Food Branch (HPFB) of Health Canada. revised October 2002, subject to change)

Name of Fibre (see note a)	Ingredient Name	Classification of Ingredient as Fibre Source		Acceptable Ingredient?	Fibre Labelling: Regular Foods (see note c)	Fibre Labelling: Meal Replacements (see note d)	
		Traditional	Novel		Include amount in dietary fibre label declaration? Claim permitted? - see items 41, 42, 43, 44 of table following B.01.513	Include amount in dietary fibre label declaration?	Claim Permitted Including "Source of Fibre"?
Apple pomace *Treetop* brand	Apple pomace powder/ Poudre de tourteaux de pommes		✓	Yes	No	No	No
Corn bran by traditional milling (less than/equal to 65% total fibre)	Corn bran/ Son de maïs	✓		Yes	Yes	Yes	No
Corn bran at greater than 65% total fibre	Corn bran/ Son de maïs		✓	Yes	No	No	No
Mustard bran	Mustard bran/ Son de moutarde		✓	Yes but only In condimental amounts	No	No	No
Inulin from chicory root (*Orafti® inulin* - Quadra Chemicals) (*Frutafit® inulin* - Sensus America) *Metamucil® FibreSure* (Procter & Gamble) Cargill's Oligo-FiberT inulin	Chicory root inulin	✓		Yes	Yes	Yes	Yes
Oat bran ≥13 % total dietary fibre, ≥ 30% of fibre as soluble fibre, and ≤ 12% moisture	Oat bran/ Son d'avoine	✓		Yes	Yes	No	No
Oat hulls - ground, bleached	Oat hull fibre/ Fibres de		✓	Yes in grain and bakery products	Yes	Yes	No

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Canadian Harvest® Oat Fiber 300-58 (Opta® Food Ingredients)	bale d'avoine			at levels that provide a source of fibre (see note b) and in bar-type meal replacements			
Pea Hull Fibres *Hi Fi Lite* & *Centara* (Nutri-Pea Limited) *Exlite Coarse* (Parrheim Foods) *Ground pea hull fibre* (Best Cooking Pulses)	Ground pea hull fibre/ Fibre de cosses de pois moulue		✓	Yes	Yes but only in bakery products and cereals *Centara and BCP may also be used in meat products where a filler/binder is permitted	No	No
Psyllium seed husk	Ground psyllium fibre/ Fibre de psyllium moulue		✓	Yes but only if individual products submitted to / accepted by HPFB	Yes (if accepted)	No	No
Rice bran *Fiberice* (Farmers Rice Cooperative)	Rice bran/ Son de riz		✓	Yes	No	No	No
Soy cotyledon *Fibrim* *300, 1000, 1010, 1250, 1250, 1255, 1450*, and *2000* by Protein Technologies International	Ground soy cotyledon fibre/ Fibre de cotylédon de soya moulue		✓	Yes	Yes	No	No
Sugar beet fibre, *Fibrex* (Delta Fibre Foods) (> 0.125 mm)	Ground sugar beet fibre/ Fibre de betterave à sucre moulue		✓	Yes	Yes but only in bakery products at less than or equal to 7%	No	No
Wheat bran, coarse (>0.75 mm)	Wheat bran/ Son de blé	✓		Yes	Yes Claim for regularity if a reasonable daily intake provides 7 g of fibre from coarse wheat bran	Yes	Yes if a serving contains 7 g of fibre from coarse wheat bran
Wheat bran, medium (0.5 - 0.75 mm)	Wheat bran/ Son de blé	✓		Yes	Yes	Yes	No
Wheat bran, fine (<0.5 mm)	Wheat bran/ Son de blé		✓	Yes	No	No	No
Wheat, starch-reduced *Fibrotein* Mohawk Oil (mean PS= 0.6 mm)	Starch-reduced wheat/ blé réduit en amidon		✓	Yes	Yes "as is" or in baked products such as bread, muffins, cookies and in low temperature	No	No

					extrusion breakfast cereals		
Whole foods: fruits, vegetables, traditionally-milled cereals (including rare grains acceptable for food use e.g. quinoa), legumes, nuts, seeds (including flaxseed), etc.	e.g. carrots/ carottes, beans/fèves	✓		Yes	Yes but must not be finely ground	Yes but must not be finely ground	No

Notes:

a) Figures in "Name of Fibre Column" refer to mean particle size as measured by the method of Mongeau, R. and R. Brassard, *Cereal Chemistry 59* (5): 413-417, 1982.

b) Oat hull fibre has not been approved for use as a bulking agent for use in calorie reduction, i.e., a claim for calorie reduction is not acceptable on a product to which oat hull fibre has been added.

c) Dietary fibre from novel fibre sources may not be calculated and declared in the Nutrition Facts table of a food unless proof of efficacy as dietary fibre in the same type of food has been shown through clinical testing to the satisfaction of Health Products and Food Branch and a letter of no objection has been issued. (Food Directorate Guideline No. 9, "Guideline Concerning the Safety and Physiological Effects of Novel Fibre Sources and Food Products Containing Them", revised November 1994, see Food Directorate Guideline No. 9, "Guideline Concerning the Safety and Physiological Effects of Novel Fibre Sources and Food Products Containing Them", revised November 1994)

d) Dietary fibre from novel fibre sources may not be calculated and declared in the Nutrition Facts table, regardless of their status in "Regular Foods" unless proof of efficacy as dietary fibre in the context of the meal replacement has been shown through clinical testing to the satisfaction of Health Products and Food Branch and a letter of no objection has been issued. (Policy Respecting Dietary Fibre in Meal Replacements, Health Products and Food Branch, September 1993.)

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nutrasource diagnostics inc.

Suite 203 - 120 Research Lane

University of Guelph Research Park

Guelph, Ontario, Canada

N1G 0B4

To: Robert Serrano, VP Technical Services, Grain Millers Inc.

CC: Carol Culhane, International Food Focus Ltd.; William Rowe, NDI

From: Maggie Laidlaw, Director of Clinical Services, NDI

Re: GRAIN MILLERS LAXATION STUDY FINAL REPORT

Date: June 19th, 2008

1. Introduction

This laxation study was undertaken in order to assess the safety and physiological efficacy of a novel oat hull fibre. Grain Miller contracted NDI to carry out the study, which was designed to follow Health Canada's "Guideline for Planning and Statistical Review of Clinical Laxation Studies for Dietary Fibre". The major elements of this study were as follows:

1. Recruitment of a free-living population.
2. Consumption of a metabolically-controlled diet by all subjects.
3. Number of subjects, length of acclimatization periods and length of stool collection periods would meet or exceed Health Canada's guidelines.
4. Adherence to the ICH Guidelines for conducting a clinical trial.
5. Prior approval by an Independent Research Ethics Board for human trials.

2. Study Objectives

2.1 Primary Objective

The primary objective of the study is to show that the novel oat fibre being tested has a positive laxation effect on the subjects in the study. The **null hypothesis** is as follows:

The average daily fecal output with the diet containing the oat hull fibre is not greater than that of the diet which does not contain the oat hull fibre, the "negative control".

The **alternative hypothesis** is as follows:

The average daily fecal output with the diet containing the oat hull fibre (and the AACC fibre) is greater than that of the negative control diet.

2.2 Secondary Objective

The secondary objective is to demonstrate that the observed average daily fecal output with the test fibre is at least 50% of the output with AACC wheat bran, the "positive control". This will allow assessment of the biological significance of the novel oat hull fibre, because the type of fibre is the only difference amongst the treatment diets and the negative control diet.

3. Study Design

3.1 Study population

The study population consisted of 12 females and 8 males, with an age range of 22 to 61 years, and an average age of 41.25 years. Six of the females were of premenopausal age, and treatment periods were timed to occur at a similar time in the menstrual cycle. Inclusion criteria were as follows:

- good health
- normal bowel function
- age between 18 and 65

Exclusion criteria consisted of the following:

- any allergies to oats or wheat
- presence of any significant illness, including gastro-intestinal conditions such as irritable bowel syndrome, Crohn's Disease or diverticulitis
- history of drug or alcohol abuse
- regular consumption of any prescription medications, OTC medications or natural health product for abnormal bowel function, such as constipation or diarrhea

3.2 Treatments

The study was designed to test both a basic white bread with added oat hull fibre, and a basic cornflake cereal with added oat hull fibre.

3.2.1 Negative Control Diet

The negative control diet consisted of a metabolic diet formulated to contain 12-15% of energy from protein, 30-35% from fat, 45-55% from carbohydrate and 16 to 21 g fibre. This fibre content would include an estimated 2 g fibre from a 50 g portion of fibre-unsupplemented cornflake-type cereal, and 2 g fibre from fibre-unsupplemented white bread , i.e. each of the two negative controls were in the same treatment period.

3.2.2 Positive Control Diet

The positive control diet for the cereal branch consisted of the basic metabolic diet (as in 3.2.1) plus 50 g AACC wheat bran supplemented cornflake cereal and one 60 g slice of white bread. The positive control diet for the bread branch consisted of the basic metabolic diet plus one 60 g slice of AACC wheat bran supplemented white bread and 50 g cornflake cereal.

3.2.3 Two test (OHF) Foods

Two test diets, each containing oat hull fibre, were formulated. One test product was an oat hull fibre cereal, and the second was an oat hull fibre bread. The test diet for the cereal branch consisted of the basic metabolic diet (as in 3.2.1) plus 50 g oat hull fibre supplemented cornflake cereal and one 60 g slice of white bread. The test diet for the bread branch consisted of the basic metabolic diet plus one 60 g slice of oat hull fibre supplemented white bread and 50 g cornflake cereal. All of the fibre-supplemented diets (AACC wheat bran or oat hull fibre) were formulated to add a further 6-7 g fibre to a 50 g portion of cereal or a 60 g slice of white bread.

3.2.4 Treatment Regime

Each diet was consumed for a period of 3 weeks, with a one-week washout period between each diet, and stool collection took place over the final 5 days of each 3-week period.

3.3 Experimental Design

3.3.1 Randomization

The study design was a crossover study, where each subject consumed each diet for a three-week period, followed by a 1-week washout period. Subjects were first randomized to one of five groups, each containing 4 subjects, and this was followed by randomization of the groups to a dietary order. For example, Group 1, with 4 subjects, consumed the diets in the following order:

Diet Period 1 – Oat Hull cereal diet
Diet Period 2 – AACC wheat bread diet
Diet Period 3 – AACC wheat cereal diet
Diet Period 4 – Oat Hull bread diet
Diet Period 5 – Negative control diet

Group 4 consumed the diets in the following order:

Diet Period 1 – Oat Hull bread diet
Diet Period 2 – Oat hull cereal diet
Diet Period 3 – AACC wheat cereal diet
Diet Period 4 – Negative control diet
Diet Period 5 – AACC wheat bread diet

The randomization procedure used was an internet program from Tufts University and the procedure was verified using SAS© statistical software at the University of Guelph (http://www.tufts.edu/~gdallal/random_block_size.htm).

Although double-blinding is ideal in a study of this type, it was difficult to maintain complete blinding, as the AACC bread and cereal were quite different in appearance than either the oat hull fibre bread and cereal, or the white bread and plain cornflake cereal. However, subjects could not determine which of the "non-white" breads was oat hull fibre bread and which was un-supplemented bread. Similarly, both the plain cereal and the oat hull cereal appeared very similar, so subjects were unable to differentiate them, and the trial coordinator was equally unaware. In addition, the subjects were not cognizant of which fibre was the test fibre. In effect, there was partial blinding of the study.

3.4 Study protocol

The study protocol was submitted to the Canadian Shield Research Ethics Board, and is presented, together with the REB attestation, in this report, as **Appendix 1**.

Figure 1, on the following page, illustrates the layout of the study, and the interventions/procedures taking place at each time-point.

3.4.1 Deviations from the Protocol

There were no major deviations from the protocol.

4. Efficacy Measures and Statistical Methods

4.1 Major and Secondary Variables

The major variable is average daily wet fecal weight expressed as total wet fecal weight divided by 5, the number of collection days. Secondary variables include frequency of defecation and individual daily stool weights. In order to assess acceptability, subjects were asked to keep a daily diary of any symptoms they experienced during the study, as well as any unexpected events that may have caused them additional stress, and diary pages were submitted to the study investigator at the end of each diet period.

4.2 Dietary Fibre Analysis and Sampling Protocol

Prior to the study initiation, the fibre content of each of the cereals and each of the breads was determined by one of the methodologies recommended by Health Canada. During the study, a sample of each batch of each bread, and each type of cereal was retained. At the conclusion of the study, the fibre content of each test product was measured to ensure accuracy of fibre content of each product throughout the study.

Figure .

LAXATION STUDY DIAGRAM

Timelines

Start 3 weeks 1 week 3 weeks 1 week 3 weeks [redacted] 3 weeks 1 week 3 weeks end

↑ [redacted] [redacted]****↑ ↑ [redacted] [redacted]****↑ ↑ [redacted] [redacted]****↑ ↑[redacted] [redacted]****↑ ↑[redacted] [redacted]****↑

Notes:

1. During each of the 3 week periods (↑....↑), subjects are provided with almost all of their daily food. The energy content of the diets is calculated to be approximately 1800 kcals, the average intake for an adult female. This ensures that all of the female subjects consume the entire diet, and therefore the required amount of fibre. Male subjects and female subjects who normally consume more than 1800 kcals in their daily diet are permitted to add foods and beverages into their diet, provided that these additional items do not contribute more than 1 additional gram of fibre per day. Examples of additional items include most beverages, milk, yogurt, cheese, etc. Permitted items that may contribute fibre are listed in **Appendix 2,** together with their fibre values, and this list is provided to subjects, with instructions to add no more than 1 additional gram of fibre (in total) to their daily diets. Moderate amounts of alcohol are also permitted.

2. During each of the 1 week periods, as well as the [redacted] December festive season, subjects are permitted to consume their normal intake of foods and beverages.

3. On day 1 of the last 5 days ([redacted]****) of each 3-week period, subjects consume the gelatin capsule provided, and collect each of their stool samples in plastic bags. Each stool sample is weighed on the scales provided, and time of collection is recorded. Each stool sample must be collected in a different plastic bag, and stool samples are then frozen for later analysis.

4. During each 3 week diet period, subjects complete a 3-day diet record [redacted] of all of their food and beverage intake.

5. During the entire study, subjects will record any adverse events in a diary provided.

4.3 Measurement of Transit Time

To measure the completeness of stool collection, and to measure transit time, each frozen stool sample was X-rayed and the number of radio-opaque rings counted. Each capsule contains 24 rings, and the manufacturer (Sitzmarks; Konsyl Pharmaceuticals Inc., Fort Worth, TX) suggests that at least 92% of the rings should be recovered during the 5-day collection period. Daily ring counts also help to determine the transit time for each fibre source. Mouth to anus transit time is determined as follows:

$$\text{Mean transit time} = \Sigma x_1 t_1 / n \text{ hours}$$

where x_1 is the number of markers present in a stool passed after time interval t_1 and n is the total number of markers excreted.

4.4 Statistical Analyses

Statistical analyses will be carried out using SAS® statistical software. Paired t-tests for repeated samples will assess any differences in average daily fecal wet weight between the negative control treatment, the two oat hull treatments and the two positive control treatments. This statistical method will also be used to assess the average fecal weight change per gram of additional dietary fibre, over and above that found in the negative control diet, as well as any statistical differences in stool frequency and in calculated transit times.

5. Results

5.1 Adverse Events

All twenty of the subjects remained in the study for the entire 21 weeks duration. Adverse events were minor and are presented in **Table 1.** None of the subjects complained of any unpalatability issues associated with any of the treatment foods or control foods. On analysis of the stool data, one subject was observed to have sluggish bowels. Although this subject did consume a capsule at the start of every stool collection period, no rings were ever observed in her stools, and her stool output was minimal on all diets, so her data was omitted from the data analysis, leaving the number of subjects at 19.

Table 1 Reported Adverse Events, by type and number of subjects

[redacted]			
gas	2	1	
cramps, sore/upset stomach	4	1	
problems with bowel movement	1		
bloating	1		
headache	3	1	
heartburn	1		
loose stools/diarrhea	1	1	

There was no pattern of adverse events on any particular diet, and none of the symptoms lasted more than a day or two. Many of the subjects did not return their diary sheets, because the only thing written on them was that there was nothing to report, or they did not complete these sheets for the same reason. They were encouraged to return them even if there was nothing to report.

5.2 Dietary Results

The metabolic diets were formulated using ESHA nutritional analysis software. Diet records from each diet of the five diet periods were analysed using the same software, and the average dietary composition* of each of the diets is listed in **Table 2.** The nutritional values for the fibre sources (AACC wheat bran and oat hull fibre) were first added as new items to the ESHA database, as were the nutritional values for the basic cornflake cereal and white bread. Next, the nutritional content of the AACC and the Oat Hull breads and cereals were assessed, and the results were added to the ESHA database. This enabled nutritional analysis of the metabolic diets plus positive control bread and cereal, and test bread and cereal. In addition, all of the test and control foods were tested for fibre content at the beginning of the study, as well as on several other occasions. The variability on results from one test lab led to a final analysis at a second lab (June 4 results) and the latter were the values that were used in all of the nutrient analyses of the diets. The results of these analyses are presented in **Table 3.**

Table 2 Average dietary composition of basic diets (± S.D.)*

[redacted]					
Negative control	1896 ± 27.0	16.8 ± 0.45	50.8 ± 1.30	32.4 ± 1.34	18.93 ± 0.52
Positive control (cereal)	1879 ± 31.4	16.8 ± 0.45	50.8 ± 1.30	32.4 ± 1.34	23.3 ± 0.52
Positive control (bread)	1893 ± 31.5	16.8 ± 0.45	50.8 ± 1.30	32.4 ± 1.34	22.8 ± 0.52
Oat hull fibre cereal	1906 ± 31.4	16.8 ± 0.45	50.8 ± 1.30	32.4 ± 1.34	22.7 ± 0.52
Oat hull fibre bread	1886 ± 31.5	16.8 ± 0.45	50.8 ± 1.30	32.4 ± 1.34	24.3 ± 0.52

*Calculated using the ESHA® nutritional analysis program

The substitution of oat hull bread or AACC wheat bread for plain white bread did not alter the energy contribution from the three major energy sources, nor did substitution of oat hull cereal or AACC wheat fibre cereal from cornflake cereal.The addition of a test fibre source (oat hull fibre or AACC wheat fibre) did not change the balance of protein, carbohydrate or fibre in any of the diets. The negative control diet was slightly higher in protein than the target values, i.e. target value was 12-15% energy from protein, and the calculated value, based on the dietary analysis, was 16.8% of energy. Both the carbohydrate and the fat were within the target ranges of 30-35% of energy from fat, 45-55% of energy from carbohydrate. Fibre was also within the target range of 16 to 21 g fibre.

Subjects were allowed to add specific foods in order to meet their energy needs. None of the female subjects added very much to their diets, other than beverages; however, the male subjects added significantly to their diets, particularly the larger and/or more physically active males. Energy intake increased up to 1000 kcals, mostly from high carbohydrate beverages such as colas, and, milk and milk products. Overall, energy from protein decreased slightly and energy from carbohydrate increased slightly. All subjects were given a list of foods, containing some fibre, from which they could choose additional items (**Appendix A**) and they were instructed to make sure that the total fibre content of all of the additional foods, in a one-day period, did not exceed 1.5 g, particularly during the week of the stool collection period. From a random review of several diets, it appears that these instructions were followed, as the fibre content among the subjects varied by only 1.3 grams, on average. The fibre content of the basic diet on weeks 3, 6, 9, 12, and 15 (the weeks when stool samples were collected) was within the original target value of 16-21 grams.

Table 3 Analysis of fibre content of test breads and cereals

PRODUCT	DATE OF ANALYSIS	TDF (%)
Negative control bread	November 11	3.7
	November 21	3.7
	April 3	5.2
	May 5	1.9
	June 4	3.1
Positive control bread	November 11	4.9
	November 21	13.1
	April 3	9.0
	May 5	8.8
	June 4	9.6
Oat Hull bread	November 11	11.2
	November 21	11.2
	April 3	13.3
	May 5	10.2
	June 4	12.1
Negative control cereal	November 11	3.2
	April 16	4.0
Positive control cereal	November 11	15.1
	December 5th	14.0
	April 3	12.8
Oat Hull cereal	November 11	5.4
	December 5	13.3
	April 3	12.0

5.3 Stool Weight Results

Stool weights are presented in **Table 4**.

Table 4 Average daily stool weights for oat hull fibre products, and positive and negative controls, during the five diet periods

[redacted]					
1	171	137	194	138	118
2	111	96	109	65	118
3	211	156	139	115	115
4	149	132	133	88	122
5	68	91	134	81	56
7	203	210	192	289	189
8	24	123	44	58	56
9	161	111	126	75	126
10	86	73	53	31	40
11	108	137	182	116	143
12	94	140	119	109	64
13	93	107	106	103	75
14	188	126	127	65	24
15	77	124	115	78	110
16	105	96	142	109	76
17	97	123	127	138	112
18	62	78	126	135	117
19	124	126	74	92	84
20	329	199	318	239	181
AVERAGE	130	126	135	112	101
SD	69.7	35.4	59.5	61.4	44.0

Note: Diet periods are as follows: OH-C=Oat hull fibre cereal; AACC-C=Positive control cereal; OH-B= Oat hull fibre bread; AACC-B= Positive control bread; Neg. C= Negative control. SD = Standard deviation

Statistical analysis of this data to determine whether there were significant differences amongst the test oat hull fibre foods, the positive control foods and the negative control foods revealed a significant difference between the oat hull fibre foods (cereal and bread) and the negative control (p=0.0484 and 0.0027, respectively), using a p-value of <0.05 for statistical significance. There was also a significant difference between the positive control and the negative control cereal (p=0.0060). There was no statistical difference between the positive control and the negative control bread (p=0.2593). There was no statistical difference in average daily stool weight between the oat hull fibre cereal and the positive control cereal (p=0.7301) but the average daily stool weight for the bread positive control was significantly lower than that for the oat hull fibre bread (P=0.0262).

A statistical analysis of the change in stool weight per gram of dietary fibre is presented in **Table 5.**

Table 5 Change in fecal output for the test products and positive controls compared to the negative control, expressed as average change in fecal output per change in dietary fibre (all values in grams)

[redacted]					
	Neg C	x	x	x	x
AVERAGE	OH-C	28.16	4.00	7.04	0.0484
SD		57.96		14.49	
AVERAGE	AACC-C	24.16	4.40	5.49	0.0060
SD		33.81		7.68	
AVERAGE	OH-B	33.37	4.50	7.42	0.0027
SD		41.82		9.29	
AVERAGE	AACC-B	11.32	2.80	4.04	0.2269
SD		39.42		14.08	

Calculations for Table 5

The average fecal weight change for each subject was calculated by subtracting the average daily fecal output during the negative control dietary period from the average daily fecal output during each of the test fibre and positive control periods. Thus, in **Table 5**, there are no values for the negative control diet, because for each of the foods, the value for the negative control is subtracted from the value for each of the test and positive control breads and cereals. All of the total dietary fibre levels of the negative control bread and cereal, as well as the oat hull test bread and cereal and the AACC wheat fibre bread and cereal were determined by

TDF analysis (**see Table 3**). The change in dietary fibre was determined by subtracting the dietary fibre content of the negative control diet from the dietary fibre content of each of the other diets. Given that all of the subjects were consuming the same metabolic diet, with the same basal fibre level, the dietary fibre contributed by a 60 g serving of the basic unsupplemented bread was 1.55 g, and of a 50 g serving of the basic unsupplemented cereal, 2.00 g, for a total of 3.55 g. The fibre content of one serving of the oat hull bread and cereal was 6.05 g and 6.00 g, respectively, and of the AACC bread and cereal, 4.8 g and 6.4 g, respectively. The calculations for each of the four diets is as follows:

Change in dietary fibre = (dietary fibre content of oat hull cereal + plain bread) –
for oat hull cereal diet (dietary fibre content of plain cereal + plain bread)
= (6.00 + 1.55) – (2.00 + 1.55) = 4.00 g

Change in dietary fibre = (dietary fibre content of AACC cereal + plain bread) –
for AACC cereal diet (dietary fibre content of plain cereal + plain bread)
= (6.40 + 1.55) – (2.00 + 1.55) = 4.40 g

Change in dietary fibre = (dietary fibre content of oat hull bread + plain bread) –
for oat hull bread diet (dietary fibre content of plain cereal + plain bread)
= (6.05 + 1.55) – (2.00 + 1.55) = 4.50 g

Change in dietary fibre = (dietary fibre content of AACC bread + plain bread) –
for AACC bread diet (dietary fibre content of plain cereal + plain bread)
= (4.80 + 1.55) – (2.00 + 1.55) = 2.80 g

To calculate the weight change per gram fibre, the stool weight change was divided by the grams fibre, for each food, e.g.

For the oat hull bread , this was 28.16/4 = 7.04

Interpretation of Results (Tables 4 and 5)

Assessment of Primary Objective:

The primary objective of the study was to show that the novel oat fibre being tested had a positive laxation effect on the subjects in the study. A positive laxation effect would be demonstrated by an increase in average daily fecal output, in comparison to the negative control. As seen in **Table 4**, both the oat hull fibre bread and cereal added to the basic metabolic diet resulted in a significant increase in average daily fecal output. Further, **Table 5** illustrates that when the average daily fecal output takes into account the average daily fibre intake, this significant difference is still maintained. Thus the null hypothesis, that '*The average daily fecal output with the diet containing the oat hull fibre is not greater than that of the diet which does not contain the oat hull fibre, the "negative control"*' is rejected, and the alternative hypothesis, that '*The average daily fecal output with the diet containing the oat hull fibre (and the AACC fibre) is greater than that of the negative control diet*', is accepted.

Assessment of Secondary Objective:

The secondary objective of the study was to demonstrate that the observed average daily fecal output with the test fibre was at least 50% of the output with AACC wheat bran, the "positive control". The fecal output of subjects on the AACC bread diet (positive control bread), having a p-value greater than 0.05, was not significantly different than the negative control (see p-values in **Table 5**). In a separate analysis (data not shown), the oat hull fibre cereal was compared to the AACC wheat fibre cereal, in terms of change in stool weight per gram of fibre, there was no significant difference between the two (p= 0.7289), nor was there a significant difference between the oat hull bread and the AACC bread, although the result was close to the significance level of <0.05, with a p-value of 0.0701. Note that the standard deviation for change in stool weight per gram of fibre was quite high in some cases, e.g. 14.49 for the oat hull cereal, and 14.08 for the AACC bread, and this may explain the lack of differentiation between the oat hull bread and the AACC bread (i.e. overlap of results). Also, the standard deviation for the change in stool weight is also quite high, although this is not unexpected in the study, given the many sources of variation inherent in a study of this type.

5.4 Stool Transit Time Results

Stool transit time is estimated as outlined in section 4.3. As well as the subject whose data was omitted from the entire analysis (see Section 5.1) the data for two other subjects was omitted from the transit time analysis. This data belonged to a married couple, and the wife did not expel any rings, while the husband expelled far more than the 24 rings enclosed in one capsule, so it is possible that the husband may have inadvertently consumed 2 capsules, while the wife consumed none, or that stool bags were mis-labelled. For all other subjects, Table 6 illustrates the results of this analysis.

Table 6 Stool cumulative transit time for each subject, on a daily basis

OH-C Avg.	1.072	9.494	16.647	23.218	24.000
OH-C SD	± 2.393	± 7.881	± 7.629	± 2.468	± 0.000
AACC-C Avg	1.765	7.088	17.493	21.376	24.000
AACC-C SD	± 4.935	± 8.243	± 6.326	± 4.887	± 0.000
OH-B Avg.	0.922	10.666	15.706	20.331	24.000
OH-B SD	± 2.959	± 6.724	± 7.431	± 4.678	± 0.000
AACC-B Avg.	0.440	11.938	16.884	21.581	24.000
AACC-C SD	± 1.143	± 7.832	± 6.287	± 4.555	± 0.000
Neg. C Avg.	0.388	5.862	10.904	18.842	24.000
Neg. C SD	± 1.518	± 6.747	± 9.498	± 8.049	± 0.000

Transit time is presented on a cumulative basis. For example, looking at the cumulative transit time (CTT) for day 3, the average CTT for the oat hull cereal, AACC cereal, oat hull bread and AACC bread appear to be very similar (16.647, 17.493, 15.706 and 16.884, respectively) whereas for the negative control this value appears to be lower (10.904). The pattern for CTTs for day 4 is similar, with a negative control value of 18.8 and all of the others above 20. Definitive differences are presented in **Table 7**, which illustrates statistical outcomes. Within each product category (OH-C, AACC-C, OH-B and AACC-B), and for each subject, the CTT for day 1, 2, 3 and 4 was subtracted from the CTT for day 1, 2, 3 and 4 for the negative control, respectively. Day 5 was not calculated because it is the same for all subjects and all product categories.

Table 7 Statistical significance of changes in cumulative transit time for the test products, positive controls and negative control

AVERAGE	OH-C	0.147	3.590	6.909	9.910
SD		± 3.475	± 11.092	± 13.488	± 11.865
p-value		0.8677	0.2150	0.0584	0.0045
AVERAGE	AACC-C	0.173	0.848	6.061	4.646
SD		± 7.112	± 8.455	± 9.852	± 9.730
p-value		0.9213	0.6848	0.0220	0.0666
AVERAGE	OH-B	0.235	3.264	5.514	6.462
SD		± 0.970	± 10.702	± 12.112	± 10.583
p-value		0.3322	0.2266	0.0789	0.0229
AVERAGE	AACC-B	-0.368	2.078	-0.039	0.503
SD		± 2.165	± 11.694	± 11.355	± 8.948
p-value		0.4931	0.4743	0.9889	0.8195

D=day, e.g. D1= day one of the stool collection period

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For both the test products and the positive controls, there was no significant difference between their cumulative transit times (CTT) for day 1 and day 2 (i.e. the first 48 hours). By Day 3 (72 hours), the positive control cereal CTT was significantly different than the negative control (p=0.0220), and the oat hull cereal and bread were close to significance (p=0.0584 and 0.0789, respectively). Day 4 (96 hrs) results were similar, with the oat hull cereal and bread both showing significant differences between their CTTs and those of the negative control. The AACC cereal p-value was close to significance, at p=0.0666. Only the AACC bread was not significantly different than the negative control in terms of CTT, with none of the p-values below 0.05. A null hypothesis stating that there is no difference in CTT amongst the oat hull foods, the positive control foods and the negative control is therefore rejected for the oat hull foods and the positive control cereal, in comparison to the negative control, but would be accepted for the positive control bread. The alternative hypothesis, that there is a significant difference in CTT amongst the oat hull foods and the positive control cereal, when compared to the negative control, is accepted.

Another way of looking at transit time is to examine the percentage of rings expelled each day, or group of days. **Table 8** shows the day-by day ring count, as well as grouped day results: Days 1 and 2, Days 3 to 5 and Days 4 and 5.

Table 8 Average percentage ring count for each product, by day

[redacted]									
Average	OH-C	4.47	35.09	29.80	27.38	3.26	39.56	60.44	30.64
SD		±9.97	±31.1	±20.0	±31.6	±10.3	±32.8	±32.8	±31.8
Average	AACC C	7.36	22.18	43.35	16.18	10.93	29.53	70.47	27.11
SD		±20.6	±33.2	±28.3	±18.7	±20.4	±34.4	±34.4	±26.4
Average	OH-B	3.84	40.60	21.00	19.27	15.29	44.44	55.56	34.58
SD		±12.3	±28.5	±21.9	±25.9	±19.5	±28.0	±28.0	±31.0
Average	AACC-B	1.83	47.91	20.61	19.57	10.08	49.74	50.26	29.65
SD		±4.76	±32.2	±27.8	±17.2	±19.0	±32.6	±32.6	±26.2
Average	Neg-C	1.53	22.89	21.01	33.08	21.49	24.43	75.33	54.57
SD		±6.33	±28.7	±24.6	±41.3	±33.5	±28.1	±27.9	±39.6

Looking at this data, and, in particular, the groupings of days, it appears that the oat hull diets had an effect on transit time, as did the positive control diets. For example, for days 1 and 2 combined, the average ring counts for the oat hull cereal and bread diets were 39.56 and 44.46, respectively, while the ring count for the negative control was only 24.43 during the first two days. For the positive control cereal and bread diets, the combined day 1 and 2 ring counts were 29.53 and 49.74 respectively. The AACC cereal count was similar to that of the negative control, but the AACC bread count was double that of the negative control. On the other hand, the highest ring count for the latter three days of the stool collection period, as well as for the final two days, was the negative control. For example, both the oat hull bread and cereal, and the positive control bread and cereal, had ring counts of between 29 and 35 for the final two days of the study, whereas the negative control had a ring count of 54.57 for this final two days of stool collection.

One may assume that a faster transit time will result in the rings moving through the gut more quickly, and hence appearing in the stools quite early in the collection period, and, similarly, a slower transit time will result in more rings appearing in the stool during the later collection days. This appears to be the case in this study, where the negative control has higher ring counts during the final two collection days, while the test products and the positive control, on the whole, have higher counts during the early to mid collection period days. Even looking at single days, the day 5 ring count for the negative control diet was 21.49, whereas for the oat hull cereal and bread, and the AACC cereal and bread, the counts were 3.26, 10.93, 15.29 and 10.08, respectively. None of the individual days showed significant differences between any of the products, except for the positive control cereal diet, where the day 3 ring % was significantly different than the day 3 ring % for the negative control (p=0.0358).

5.5 Stool Frequency

Table 9 represents the number of stools excreted per day for each subject.

Table 9 Average stool count per day during the five day collection period

[redacted]	
OH-C	**5.05 ± 2.15**
AACC-C	**5.05 ± 2.15**
OH-B	**4.79 ± 1.65**
AACC-B	**4.47 ± 1.43**
Negative Control	**4.47 ± 2.01**

Statistical analysis of the stool counts revealed no significant differences among any of the diets. This indicates that there was no increase in frequency of bowel movement for any one diet, throughout the study.

6. Summary

A) Primary Objective

To reiterate, the primary objective of the study was to show that the novel oat fibre being tested had a positive laxation effect on the subjects in the study. The results of this study indicate that oat hull fibre, when added to a cornflake-based cereal, does have a positive laxation effect, as illustrated by the following:

- average daily fecal weight for oat hull bread and cereal, compared to negative control (130 g and 135 g Vs. 101 g, respectively) – **Table 4.**

- the change in cumulative transit time, in comparison with the negative control, by Day 4 of the stool collection period (e.g. statistically significant values of 9.91 for the oat hull cereal and close to significant change of 4.646 for the positive control, relative to the negative control) – **Table 7.**

- the non-statistical trend for more stool rings to be excreted earlier in the 5-day collection period, for both the oat hull fibre cereal and bread, compared with the negative control, where more of the rings appeared to be excreted later in the 5-day collection period - **Table 8.**

Given all of the above, the null hypothesis of no difference between the oat hull foods and the negative control is firmly rejected and the alternative hypothesis of a positive effect of the oat hull foods is accepted.

B) Secondary Objective

The secondary objective was to demonstrate that the observed average daily fecal output with the test fibre was at least 50% of the output with AACC wheat bran, the "positive control". This study has demonstrated that the oat hull foods far surpassed this objective, as shown by the following:

- the average daily fecal output for the oat hull fibre bread and cereal was similar to, or greater than, those of the AACC bread and cereal - 130 and 126 for the oat hull cereal and the AACC cereal, respectively, and 135 and 112 for the oat hull bread and the AACC bread, respectively) – **Table 4**

- the change in fecal output per change in grams of total dietary fibre (7.04 and 5.49 g, for the oat hull fibre cereal and the AACC cereal, respectively) – **Table 5.** This difference, for the oat hull fibre cereal, was 128% of the difference for the positive control, vastly surpassing the minimum Health Canada requirement of a 50% difference.

For the oat hull fibre bread, the comparison with the AACC positive control bread was difficult to make, given the relatively poor performance of the AACC bread, relative to both the oat hull fibre bread and the negative control. For example, the positive control bread change in fecal output per gram of dietary fibre was not significantly different than that of the negative control (**Table 5**). The average daily fecal weight for the positive control bread appeared to be similar to the negative control (112, and 101, respectively), whereas the positive control cereal value was 126 and the oat hull cereal and bread values were 130 and 135, respectively (**Table 4**).

Although the day 4 cumulative transit time for the positive control bread was not significantly different than the value for the negative control (**Table 7**), this parameter was not significantly different for the positive control cereal either, although it was close to significance at p=0.0666. Also, the transit time value of 21.581 was very similar to the value for the positive control cereal (21.376), as seen in **Table 6**, and the pattern of ring excretion appeared to be more similar to both the positive control cereal and the oat hull foods than to the negative control pattern (**Table 8**).

In all instances where the oat hull fibre bread, the test bread, is compared to the positive control bread, the test bread appears superior. Even in comparison to the positive control cereal, the test bread appears as good as the positive control cereal (a comparison of the test bread with the positive control bread is questionable, as mentioned previously).

For example, the average daily fecal output for the oat hull bread was highest of all the diets, at 135 g/day (**Table 4**), as was the change in fecal output per change in grams of total dietary fibre (7.42 g), in **Table 5**. The Day 4 cumulative transit time for the positive control bread was over 20, as were the values for all of the diets, except for the negative control, which was 18.842. The change in cumulative transit time was higher than that of the positive control cereal, as illustrated in **Table 7** (6.462 and 4.646, respectively), and this value for the positive control bread was also significantly different than that of the negative control (0.503). The pattern of ring output was similar to that of the other diets, except for the negative control; for example, the day 2 ring %

was higher than both the oat hull cereal and the positive control cereal, as illustrated in **Table 8** (40.60, 35.09 and 22.18, respectively).

The lack of statistical significance in the stool frequency data is indicative of the fact that although the average stool output was greater in the test and positive control diets than in the negative control diets, it did not result in a greater frequency of bowel evacuation. Thus the test and positive control foods appear to cause a greater bulk of feces, probably related to the water-holding capacity of the fibre sources, rather than a greater frequency of fecal output. This was further reinforced by a lack of complaints from the subjects with regard to symptoms of diarrhea. For the average free-living North American, no change in stool frequency is probably a desirable outcome.

Overall, the study data demonstrates that the oat hull fibre cereal and bread are at least equivalent to AACC wheat bran fibre in their laxation capacity, and this fibre source appears to be a safe and efficacious source of fibre in the diet of free-living subjects.

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Pages 000074 - 000079 have been removed in accordance with copyright laws. Please see appended bibliography list of the references that have been removed from this request.

SUBMISSION END

Reference List for Industry Submission, GRN 000261

Pages	Author	Title	Publish Date	Publisher	BIB_Info
000025 - 000028	Galdeano, Melicia Cintia; Grossmann, Maria Victoria Eiras	Oat Hulls Treated With Alkaline Hydrogen Peroxide Associated With Extrusion As Fiber Source In Cookies	Jan.-Mar. 2006	Ceienc. Tecnol. Aliment.. Campinas	Volume 26, Number 1, pgs 123-126
000030 - 000038	Fernandez-Garcia, Estrella; McGregor, John U.; Traylor, Sandra	The Addition of Oat Fiber and Natural Alternative Sweeteners in the Manufacture of Plain Yougurt	1998	Journal of Dairy Science	Volume 81, Number 3, pgs 655-663
000040 - 000044	Stephen, Alison M.; Dahl, Wendy J.; Johns, Dianne M.; Englyst, Hans N.	Effect of Oat Hull Fiber or Human Colonic Function and Serum Lipids	1997	Cereal Chemistry	Volume 74, Number 4, pgs 379 - 383
000074 - 000079	Weickert, Martin O.; Mohlig, Mattihias; Schofl, Christof; Arafat, Ayman M.; Otto, Barbel; Viehoff, Hannah; Koebnick, Corinna; Kohl, Angela; Spranger, Joachim; Pfeiffer, Andreas F.H.	Cereal Fiber Improves Whole-Body Insulin Sensitivity in Overweight and Obese Women	April 2006	Diabetes Care	Volume 29, Number 4, pgs 775-780

NA- Not applicable

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September 2, 2008

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Dr. Laura Tarantino, Director
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Re: Additional Data for GRAS Notification for Grain Millers, Inc.'s Oat Fiber

Dear Dr. Tarantino:

We received a call from the Food and Drug Administration's ("FDA") Office of Food Additive Safety on August 20, 2008 requesting additional information on food applications in connection with the GRAS Notification submitted by Grain Millers, Inc. for Oat Fiber. Specifically, FDA requested more detail on the kinds of food categories in which the ingredient is used.

Oat fiber is added to foods seeking to have increased fiber in the following product categories:

Bread/pizza crust
Cookies/crackers/bars (cold extruded and baked)
Cereal (hot and cold)
Baby food cereal
Snacks (fried and baked)

Oat Fiber is added to the above food categories at levels ranging from 5% to 14% (w/w) in amounts necessary to meet FDA regulatory food standards for various nutrient content claims, including, but not limited to, "high fiber," "excellent source," "good source," "calorie reduced," and "low carbohydrate" claims.

Oat Fiber is used as a functional ingredient in breaders and batters applied in coating onto meat and poultry, i.e., to improve yield, adhesion and texture. Oat Fiber is also used in some meat products as an extender. USDA recognizes oat fiber as an ingredient added to meat and poultry products and references oat fiber in its Food Standard Labeling and Policy Book (2005) p 125, *available at* http://www.fsis.usda.gov/OPPDE/larc/Policies/Labeling_Policy_Book_082005.pdf (Attachment 1). The use of Oat Fiber in meat and poultry products is described in more detail in Attachment 2.

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As the applications of Oat Fiber includes uses in meats, we provide to FDA an additional copy of the original GRAS Notification and this letter to forward to FSIS.

If you have questions or require additional information, please contact me at (202) 778-9124.

Sincerely Yours,

[redacted] (b)(6)

Gary L. Yingling

cc: Grain Millers, Inc.

Attachments

Attachment 1

UNITED STATES DEPARTMENT OF AGRICULTURE

Food Safety
And Inspection
Service

Office of Policy, Program and
Employee Development

August 2005

Food Standards and Labeling Policy Book

Revised for Web Publication August 2005
Replaces Publication Dated May 2003 and Removal of Publication Dated 1996

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PREFACE

The Policy Book is intended to be guidance to help manufacturers and prepare product labels that are truthful and not misleading. Compliance with the requirements set forth in this publication does not, in itself, guarantee an authorization. On receipt of the label application, consideration will be given to suitability of ingredients statements, preparation, and packaging so as not to mislead the consumer. Adherence to the product and label requirements in this Policy Book does not necessarily guarantee against possible infringement of all related patents, trademarks or copyrights.

Changes in this publication are to add new entries, correct errors, condense material, and reformat the entries for ease in reading and use. There will be updates of the publication to conform to changes in meat and poultry inspection standards and to reflect any current policy developments.

Errors found in this issue should be reported through channels to your district office.

OAT FIBER:

"Oat fiber," should be identified in the ingredients statement as "isolated oat product." It may be used in non-standardized products and in products, such as, "taco fillings."

OLEOMARGARINE:

The Establishment Number may be omitted from the outer container, provided that articles are completely labeled including Establishment Number inside.

See: 9 CFR 317.2(i)

OMELET, DENVER OR WESTERN STYLE:

Product must contain at least 18 percent ham with onions and green and/or red peppers.

OMELET, FLORENTINE:

Product must contain at least 9 percent cooked meat and must contain spinach.

OMELETS WITH:

Bacon - must contain at least 9 percent cooked bacon

Chicken Livers - must contain at least 12 percent cooked liver

Corned Beef Hash - must contain at least 25 percent corned beef hash

Creamed Beef - must contain at least 25 percent creamed beef

Ham - must contain at least 18 percent cooked ham

Sausage - must contain at least 12 percent dry sausage

Sausage and Cheese, (omelet with pepperoni, cheese and sauce) - must contain at least 9 percent sausage in the total product.

OPEN DATING:

Labels showing further qualifying phrases in addition to the explanatory phrase must submit with the application sufficient documentation to support these additional claims. See (9 CFR 317.8(b)(32) and 9 CFR 381.129(c).) Some local authorities require that packaged foods heated and sold hot from industrial catering vehicles be dated with the day the foods were placed in the warming units (e.g., Tuesday, Friday, etc.). When assured by the local authorities that the foods are under a rigid local inspection program, the designations may be approved without an explanatory statement as required by the

Attachment 2

Use of Oat Fiber in Meat/Poultry Products

USDA recognizes oat fiber as an ingredient added to meat and poultry products and references oat fiber in its Food Standards Labeling and Policy Book (2005) p. 125, *available at* http://www.fsis.usda.gov/OPPDE/larc/Policies/Labeling_Policy_Book_082005.pdf. Oat Fiber is added onto meat and poultry as a functional ingredient in coatings (breaders and batters). Oat Fiber is added at levels ranging from 2% to 5% in coatings for meat and poultry products. The upper range of use is at 5% (w/w) of the dry coating system (breader and batter) and no more than 2% w/w of total food system (breaded or coated meats).

Also in meat products, in addition to the use in coatings, Oat Fiber is used as an extender. The common use of Oat Fiber as an extender in meats is at a low percentage and is normally in ground meats, e.g., taco and hamburger meats. Oat Fiber is mixed with other parts of the oats in a blend and added to meat as an extender, adding weight both dry and wet due to the high water absorption quality of the fiber. The Oat Fiber also prevents dehydration of the water and rendering of the fat upon heating.

The economic and functional demonstrated level of the use of Oat Fiber as an extender ranges from 3% to 5%.

The following application is an example of the extender use of the Oat Fiber in a blend: 388 g meat (67% lean ground beef) + 80 g water + 12 g Oat Fiber blend. After cooking, the product has 48.74 g free liquid weight, 0/55% water/oil, and 72.3% yield.

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September 11, 2008

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Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Re: Additional Copy of the GRAS Notification Submission and Subsequent Letter by Grain Millers, Inc.

Dear Dr. Tarantino:

As noted in our September 2, 2008 submission to FDA, which amends the original GRAS notification submitted by Grain Millers, Inc. for Oat Fiber, the applications of Oat Fiber includes uses in meats. Accordingly, we provide to FDA an additional copy of the original GRAS Notification and the September 2, 2008 letter to forward to FSIS. We apologize for not including the additional copies in our September 2, 2008 submission to FDA.

If you have questions or require additional information, please contact me at (202) 778-9124.

Sincerely Yours,

[redacted] (b)(6)

Gary L. Yingling

cc: Grain Millers, Inc.

Enclosures

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RECEIVED
SEP 18 2008
BY [redacted] (b)(6)

\M

Mcmahon, Carrie

From: Higgins, Lorraine A. [Lorraine.Higgins@klgates.com] on behalf of Yingling, Gary L. [Gary.Yingling@klgates.com]

Sent: Tuesday, December 16, 2008 3:30 PM

To: Mcmahon, Carrie

Subject: Grain Millers - Supplement Info for oat fiber GRN (372187-1 12/16/2008 03:21:30 PM)

Attachments: DC-#1281596-v1-Grain_Millers_-_Supplement_Info_for_oat_fiber_GRN_(372187-1_12_16_2008_03_21_30_PM).PDF

Please see the attached correspondence regarding GRN 261. A hard copy will follow by Federal Express.

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Attachment

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December 16, 2008

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By Email and Overnight Delivery

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Re: Supplemental Information for Oat Fiber GRAS Notification (GRAS Notice No. GRN 261),

Dear Dr. McMahon:

This letter responds to FDA's questions concerning the GRAS Notice No. GRN 261 submitted on September 11, 2009 for Oat Fiber, an insoluble fiber processed from oat hulls. In a phone call to Gary Yingling on Friday, December 5, 2008, FDA asked for the following:

1. Data on the contaminants referenced in Section 2.1

FDA requests specification limits on the residues, mycotoxins, and heavy metals referenced in Section 2.1.

As stated in the GRAS Notification, the residues and heavy metals shall not exceed Food Chemicals Codex (FCC) standards, and the mycotoxins shall not exceed FDA and USDA standards. The standards being used by Grain Millers for the Oat Fiber are as follows:

PESTICIDE RESIDUE LIMITS

	Detection Limit in Water (ppm)
Carbamates	
Aldicarb	0.2
Carbaryl	7.0
Carbofuran	0.1
Mesurol	5.0
Methomyl	1.0
MIPC (isoprocarb)	2.0
Oxamyl	1.0
Propoxur	2.0
Organophosphates	
DDVP (Vapona)	3.0

Methamidophos	4.0
Mevinphos	2.0
Thiophosphates	
Aspon	5.0
Azinphos-Methyl	0.3
Chlorpyrifos-Ethyl	0.7
Chlorpyrifos-Methyl	1.0
Diazinon	2.0
EPN	0.2
Fenitrothion	1.5
Malathion	2.0
Metasystox-R	20.0
Methyl Parathion	4.0
Parathion	2.0
Phorate	3.0
Phosmet	1.0
Phosvel	0.8

MYCOTOXINS

Deoxynivalenol (DON or Vomitoxin) ≤ 1 ppm
Aflatoxin .... ≤ 10 ppb

HEAVY METALS

Lead................≤ 0.5 ppm
Arsenic............≤ 0.5 ppm
Cadmium..........≤ 0.5 ppm
Mercury...........≤ 0.025 ppm

We also direct FDA's attention to Section 5.3 of the GRAS Notification, which provides the test results for microbes, mycotoxins, and heavy metals in a sample batch of Oat Fiber and the methodologies used in the evaluation process. These results reflect typical figures in representative batches of Oat Fiber.

2. Clarification on the different insoluble fiber figures in Section 3

FDA notes that there is a reference to 89% insoluble dietary fiber in the first paragraph in Section 3, and a reference to 84.5% insoluble fiber in the chart under Section 3.2 Physical/Chemical Specifications appearing on the same page. FDA requests clarification for the different numbers.

The reference to 89% insoluble fiber is the approximate dry weight basis value derived from a "sample batch" of Oat Fiber. The 84.5% reference in the chart is the "specification," which is expressed on an "as is" basis (i.e., with whatever moisture that naturally exists in the Oat Fiber). Therefore, the specification for the Oat Hull is not less than 84.5% (as is) insoluble fiber.

3. Discussion of oat hulls and their composition and why data for other parts of the oat kernel is relevant to the safety of the hulls

FDA has requested additional information and an explanation of why the composition of oat kernel demonstrates scientifically that the difference between oat hulls and the other parts of the oat kernel are so similar that data establishing the safety of other parts of the oat kernel confirm the safety of oat hulls.

As explained in the GRAS Notification, the whole oat kernel, including the bran layers and the hulls, are well described in published literature. The oat kernel components are common throughout the various parts of the kernel. The composition of the oat hull and oat bran fiber-tissues is principally a mixture of non-starchy polysaccharides (soluble and insoluble) that are integral components of the plant's cell wall or intercellular structure. These tissues also include proteins, starch, lipids, vitamins, minerals, and phytonutrients including non-starchy polysaccharide-bound phenolic compounds such as lignin. The latter is cross-linked to cellulose, which affects cell wall rigidity.

The difference between the different parts of the kernel resides in the proportionality of the non-starchy polysaccharide-bound phenolic compounds (e.g., lignin) or lignocellulose content, which affects the characteristic of the crystallinity of the oat kernels' outer most tissues, oat bran layers, and the hull. In addition, the non-starchy polysaccharides, principally celluloses and hemicelluloses, consist of polymers differing both in mono-saccharide-sequencing (primarily hexoses and pentoses) and bond configuration. Further, the ratio or distribution of starchy to non-starchy polysaccharides decreases from the core of the oat kernel to its periphery. As a result, the different proportions or ratios of common components create textural variability, i.e., different ratios of flexible (amorphous) polysaccharides versus rigid (crystalline) configurations of the non-starchy polysaccharides

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in and around cell wall structure. Scientifically, except for the different proportion of the components, there is no difference in the composition of the different parts of the oat kernel.

For example, oat bran will characteristically have, in addition to all of the above cell wall components, a large amount of starch (41.0-52.6%) together with amounts of soluble cell-wall fibers (5.6-9.4%), principally mixtures of (1-3, 1-4) cross-linked beta-glucans, making it more texturally appealing.[1] In summary, we enclosed tables 1, 2 and 3 to further illustrate that the oat kernel components are common throughout the various tissues, oat bran and hull in particular, and, therefore, there are no new safety issues presented by oat hulls. The published data supporting the safety of oats scientifically supports the safety of oat hull fiber because the basic components are the same.

Different types of mechanical modifications, refinements, and/or purifications affect the texture of the tissues. Grain Miller's Oat Fiber is derived by certain hydrothermal and mechanical processes to render the crystalline (rigid) structures of the oat hulls' non-starchy polysaccharides (primarily the cellulosic and hemicellulosic strands) amorphous (flexible) without the use of chemical agents or removal of naturally occurring components. The naturally occurring components originally found in the oat hull are preserved during the processing method, but the crystalline cellulosic and hemicellulosic tissues of the oat hull are made more water absorbent.

Thus, Grain Miller's Oat Fiber is basically the same tissue as non-treated oat hulls and does not raise any new safety issues. Therefore, the published data supporting the safety of oats also supports the safety of oat hulls, and, therefore, supports the safety of Grain Miller's Oat Fiber.

Sincerely,

[redacted] (b)(6)

Gary L. Yingling

cc: Grain Millers, Inc.

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[1] Marlett, J.A. 1993.Comparisons of Dietary Fiber and Selected Nutrient Compositions of Oat and Other Grain Fractions. Oat Bran. Peter J. Wood. American Association of Cereal Chemistry, St. Paul, MN.

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December 16, 2008

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DEC 17 2008
BY: (b)(6)

By Email and Overnight Delivery

Carrie H. McMahon, Ph.D.
Consumer Safety Officer
Office of Food Additive Safety (HFS-200)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835

Re: Supplemental Information for Oat Fiber GRAS Notification (GRAS Notice No. GRN 261),

Dear Dr. McMahon:

This letter responds to FDA's questions concerning the GRAS Notice No. GRN 261 submitted on September 11, 2009 for Oat Fiber, an insoluble fiber processed from oat hulls. In a phone call to Gary Yingling on Friday, December 5, 2008, FDA asked for the following:

1. Data on the contaminants referenced in Section 2.1

FDA requests specification limits on the residues, mycotoxins, and heavy metals referenced in Section 2.1.

As stated in the GRAS Notification, the residues and heavy metals shall not exceed Food Chemicals Codex (FCC) standards, and the mycotoxins shall not exceed FDA and USDA standards. The standards being used by Grain Millers for the Oat Fiber are as follows:

PESTICIDE RESIDUE LIMITS

	Detection Limit in Water (ppm)
Carbamates	
Aldicarb	0.2
Carbaryl	7.0
Carbofuran	0.1
Mesurol	5.0
Methomyl	1.0
MIPC (isoprocarb)	2.0
Oxamyl	1.0
Propoxur	2.0
Organophosphates	
DDVP (Vapona)	3.0

Methamidophos	4.0
Mevinphos	2.0
Thiophosphates	
Aspon	5.0
Azinphos-Methyl	0.3
Chlorpyrifos-Ethyl	0.7
Chlorpyrifos-Methyl	1.0
Diazinon	2.0
EPN	0.2
Fenitrothion	1.5
Malathion	2.0
Metasystox-R	20.0
Methyl Parathion	4.0
Parathion	2.0
Phorate	3.0
Phosmet	1.0
Phosvel	0.8

MYCOTOXINS

Deoxynivalenol (DON or Vomitoxin) ≤ 1 ppm
Aflatoxin .... ≤ 10 ppb

HEAVY METALS

Lead................≤ 0.5 ppm
Arsenic............≤ 0.5 ppm
Cadmium..........≤ 0.5 ppm
Mercury...........≤ 0.025 ppm

We also direct FDA's attention to Section 5.3 of the GRAS Notification, which provides the test results for microbes, mycotoxins, and heavy metals in a sample batch of Oat Fiber and the methodologies used in the evaluation process. These results reflect typical figures in representative batches of Oat Fiber.

2. Clarification on the different insoluble fiber figures in Section 3

FDA notes that there is a reference to 89% insoluble dietary fiber in the first paragraph in Section 3, and a reference to 84.5% insoluble fiber in the chart under Section 3.2 Physical/Chemical Specifications appearing on the same page. FDA requests clarification for the different numbers.

The reference to 89% insoluble fiber is the approximate dry weight basis value derived from a "sample batch" of Oat Fiber. The 84.5% reference in the chart is the "specification," which is expressed on an "as is" basis (i.e., with whatever moisture that naturally exists in the Oat Fiber). Therefore, the specification for the Oat Hull is not less than 84.5% (as is) insoluble fiber.

3. Discussion of oat hulls and their composition and why data for other parts of the oat kernel is relevant to the safety of the hulls

FDA has requested additional information and an explanation of why the composition of oat kernel demonstrates scientifically that the difference between oat hulls and the other parts of the oat kernel are so similar that data establishing the safety of other parts of the oat kernel confirm the safety of oat hulls.

As explained in the GRAS Notification, the whole oat kernel, including the bran layers and the hulls, are well described in published literature. The oat kernel components are common throughout the various parts of the kernel. The composition of the oat hull and oat bran fiber-tissues is principally a mixture of non-starchy polysaccharides (soluble and insoluble) that are integral components of the plant's cell wall or intercellular structure. These tissues also include proteins, starch, lipids, vitamins, minerals, and phytonutrients including non-starchy polysaccharide-bound phenolic compounds such as lignin. The latter is cross-linked to cellulose, which affects cell wall rigidity.

The difference between the different parts of the kernel resides in the proportionality of the non-starchy polysaccharide-bound phenolic compounds (e.g., lignin) or lignocellulose content, which affects the characteristic of the crystallinity of the oat kernels' outer most tissues, oat bran layers, and the hull. In addition, the non-starchy polysaccharides, principally celluloses and hemicelluloses, consist of polymers differing both in mono-saccharide-sequencing (primarily hexoses and pentoses) and bond configuration. Further, the ratio or distribution of starchy to non-starchy polysaccharides decreases from the core of the oat kernel to its periphery. As a result, the different proportions or ratios of common components create textural variability, i.e., different ratios of flexible (amorphous) polysaccharides versus rigid (crystalline) configurations of the non-starchy polysaccharides in and around cell wall structure. Scientifically, except for the different proportion of the components, there is no difference in the composition of the different parts of the oat kernel.

For example, oat bran will characteristically have, in addition to all of the above cell wall components, a large amount of starch (41.0-52.6%) together with amounts of soluble cell-wall fibers (5.6-9.4%), principally mixtures of (1-3, 1-4) cross-linked beta-glucans, making it more texturally appealing.[1] In summary, we enclosed tables 1, 2 and 3 to further illustrate that the oat kernel components are common throughout the various tissues, oat bran and hull in particular, and, therefore, there are no new safety issues presented by oat hulls. The published data supporting the safety of oats scientifically supports the safety of oat hull fiber because the basic components are the same.

Different types of mechanical modifications, refinements, and/or purifications affect the texture of the tissues. Grain Miller's Oat Fiber is derived by certain hydrothermal and mechanical processes to render the crystalline (rigid) structures of the oat hulls' non-starchy polysaccharides (primarily the cellulosic and hemicellulosic strands) amorphous (flexible) without the use of chemical agents or removal of naturally occurring components. The naturally occurring components originally found in the oat hull are preserved during the processing method, but the crystalline cellulosic and hemicellulosic tissues of the oat hull are made more water absorbent.

Thus, Grain Miller's Oat Fiber is basically the same tissue as non-treated oat hulls and does not raise any new safety issues. Therefore, the published data supporting the safety of oats also supports the safety of oat hulls, and, therefore, supports the safety of Grain Miller's Oat Fiber.

Sincerely,

[redacted] (b)(6)

Gary L. Yingling

cc: Grain Millers, Inc.

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[1] Marlett, J.A. 1993.Comparisons of Dietary Fiber and Selected Nutrient Compositions of Oat and Other Grain Fractions. Oat Bran. Peter J. Wood. American Association of Cereal Chemistry, St. Paul, MN.

TABLE 1
Proximate Compositions
(% dry wt) of Different Fractions of Oat Grain

	Protein	Fat	Ash	CHO[a]	Data from
Groat					
Froker	16.2	8.4	2.4	NR[b]	Youngs, 1974
Goodland	21.5	8.8	2.7	NR	Youngs, 1974
Hinoat	24.4	6.6	2.3	66.7	Ma, 1983
Oxford	14.0	4.4	2.3	NR	Zarkadas et al, 1982
Sang					
1980	11.8	NA[c]	2.8	NR	Salomonsson et al, 1984
1981	12.4	NA	2.7	NR	Salomonsson et al, 1984
Selma	14.9	7.6	1.7	75.8	Frølich and Nyman, 1988
Sentinel	16.8	6.9	2.4	73.9	Ma, 1983
	12.4	6.6	2.2	NR	Zarkadas et al, 1982
SV78559	10.7	7.4	2.9	79.0	Aman and Hesselman, 1984
NS[d]	13.2	7.4	1.9	77.5	Sanchez- Marroquin et al, 1986
Bran					
Froker	20.0	9.6	4.5	NR	Youngs, 1974
Goodland	26.8	11.2	4.4	NR	Youngs, 1974
Hinoat	19.5	1.8	9.1	69.6	Ma, 1983
Sang, 1980	12.1	NA	8.1	NR	Salomonsson et al, 1984
Selma	17.1	7.7	2.5	72.6	Frølich and Nyman, 1988
Coarse					
Fine	16.8	8.6	2.3	72.3	Frølich and Nyman, 1988
Sentinel	17.5	2.7	7.5	72.3	Ma, 1983
Mother's	5.5	1.0	2.8	90.7	Chen et al, 1988
Quaker	19.9	7.6	3.1	69.4	Shinnick et al, 1988
Wild	25.9	12.2	4.4	57.5	Sosulski and Wu, 1988
Hull					
Unprocessed	3.9	1.3	4.7	90.1	Dougherty et al, 1988.
Selma	6.6	2.8	5.7	84.9	Frølich and Nyman, 1988
Bleached	0.8	0.1	2.3	96.8	Dougherty et al, 1988
	<0.5	-0.1	NA	NR	Lopez-Guisa et al, 1988
Processed[e]	2.8	1.8	NA	NR	Lopez-Guisa et al, 1988
NS	6.3	NA	6.5	NR	Garleb et al, 1988

[a]Carbohydrate.
[b]Not reported.
[c]Not analyzed.
[d]Not specified.
[e]Coated with 10% (by wt) starch.

TABLE 2
Composition (% dry wt) of the Soluble and Insoluble Dietary Fiber in Different Fractions of Oat Grain

	Soluble				Insoluble						
	Neutral Sugars	Uronic Acids	β-Glucan	Total	Neutral Sugars	Uronic Acids	β-Glucan	Klason Lignin	Total	Total Fiber	Data from[a]
Whole kernel											
Sang	1.4	UA[b]	INC[c]	NC[d]	20.5	1.1[e]	INC	5.3	NC	28.3	E
Groat											
Oatmeal	1.0	0.1	3.8	4.9	3.0	0.3	0.6	3.3	7.2	12.1	F
Selma	2.9	0.1	INC	3.0	5.6	0.4	INC	2.0	8.0	11.0	C
Coarse	4.7	0.1	INC	4.8	2.9	0.1	INC	NA[f]	3.0	7.8	B
Porridge	3.9	0.1	INC	4.0	3.0	0.1	INC	NA	3.1	7.1	B
Rolled oats	5.3	0.1	INC	5.4	3.9	0.2	INC	1.0	5.1	10.6	A
Bran											
Sang	1.1	UA	INC	NC	21.5	1.3	INC	7.3	NC	31.2	E
NS[g]	1.6	0.1	5.3	7.0	5.0	0.3	2.2	3.8	11.3	18.3	F
Selma											
Coarse	5.6	0.1	INC	5.7	5.9	0.5	INC	3.0	9.4	15.1	C
Fine	5.2	0.1	INC	5.3	6.9	0.4	INC	3.0	10.3	15.6	C
NS	7.7	0.1	INC	7.8	6.3	0.4	INC	1.6	8.3	16.1	A
Bran plus germ	8.3	0.1	INC	8.4	5.3	0.2	INC	NA	13.7	22.1	B
Hull											
Unprocessed	0.3	0.1	NA	0.4	56.7	1.8	NA	20.0	78.5	78.9	C
Processed[h]	0.5	0.1	0	0.6	60.4	1.5	0	17.5	79.4	80.0	D
Bleached	3.7	0.2	0	3.9	69.1	1.1	0	11.4	81.6	85.5	D

[a]A, Anderson and Bridges (1988); B, Cummings and Englyst (1987); C, Frølich and Nyman (1988); D, Lopez-Guisa et al (1988), E, Salomonsson et al (1984); F, Shinnick et al (1988).
[b]Unavailable; included with insoluble fiber uronic acids.
[c]Not analyzed separately but included in neutral sugars.
[d]Not calculable, since soluble uronic acids are included in the insoluble uronic acids.
[e]Includes uronic acids from soluble fiber fraction.
[f]Not analyzed.
[g]Not specified.
[h]Coated with 10% (by weight) starch.

TABLE 3
Neutral Sugar Composition of Soluble and Insoluble Dietary Fiber from Different Fractions of Oat Grain

	Soluble, % of neutral sugars						Insoluble, % of neutral sugars						
	Glc[a]	Xyl	Ara	Man	Gal	Rha	Glc	Xyl	Ara	Man	Gal	Rha	Data from[b]
Groat													
Oatmeal	87	5	7	1	0	0	42	29	20	4	5	ND[c]	E
Sang	78	6	8	2	6	T[d]	45	45	7	1	2	T	D
Selma	88	3	3	3	3	NA[e]	54	25	16	3	2	NA	B
Oatmeal, coarse	94	2	2	T	2	T	34	38	28	T	T	T	A
Porridge oats	87	5	5	T	3	T	37	33	23	3	3	T	A
Bran													
Quaker	81	5	6	3	5	ND	45	29	18	3	5	ND	E
Sang	61	13	13	2	11	T	45	45	7	1	2	T	D
Selma, coarse	91	2	3	Tr[f]	4	NA	49	30	18	2	1	NA	B
Selma, fine	86	4	4	2	4	NA	54	23	17	3	3	NA	B
Bran plus germ	92	1	5	Tr	2	T	35	39	25	Tr	Tr	T	A
Hull													
Selma, unprocessed	67	Tr	Tr	Tr	33	NA	52	39	6	Tr	3	NA	B
Processed[g]	61	16	14	0	9	ND	45	49	4	0	2	ND	C
Bleached	8	77	14	0	1	ND	49	45	6	0	Tr	ND	C

[a]Glc = glucose, Xyl = xylose, Ara = arabinose, Man = mannose; Gal = galactose, Rha = rhamnose.
[b]A, Cummings and Englyst (1987); B, Frølich and Nyman (1988); C, Lopez-Guisa et al (1988); D, Salomonsson et al (1984); E, Shinnick et al (1988).
[c]Not detected. Rha and Gal coelute by high-performance liquid chromatographic method used.
[d]Trace, concentration not specified.
[e]Not analyzed.
[f]Trace, <0.05 g/100g.
[g]Coated with 10% (by wt) starch.

\M

Mcmahon, Carrie

From: Hsieh, Grace [Grace.Hsieh@klgates.com]
Sent: Wednesday, December 17, 2008 11:19 AM
To: Mcmahon, Carrie
Cc: Yingling, Gary L.
Subject: Grain Millers - attachment to supplement
Attachments: DC-#1281888-v1-Grain_Millers_-_attachment_to_supplement_(372570-1_12_17_2008_11_13_52_AM).PDF

Dear Carrie,

We neglected to include the attachment to the letter that we emailed to you yesterday. Please find it attached as a PDF. The hardcopy that should arrive today will have the attachment. We apologize for the inconvenience.

Best Regards,

Grace

Grace Hsieh
K&L Gates LLP
1601 K Street, N.W.
Washington, D.C. 20006-1600
202.778.9117 (direct)
202.778.9100 (fax)
grace.hsieh@klgates.com
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Attachment

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	<0.5	-0.1	NA	NR	Lopez-Guisa et al, 1988
Processed[e]	2.8	1.8	NA	NR	Lopez-Guisa et al, 1988
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Coarse	4.7	0.1	INC	4.8	2.9	0.1	INC	NA[f]	3.0	7.8	B
Porridge	3.9	0.1	INC	4.0	3.0	0.1	INC	NA	3.1	7.1	B
Rolled oats	5.3	0.1	INC	5.4	3.9	0.2	INC	1.0	5.1	10.5	A
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Bleached	3.7	0.2	0	3.9	69.1	1.1	0	11.4	81.6	85.5	D

[a]A, Anderson and Bridges (1988); B, Cummings and Englyst (1987); C, Frølich and Nyman (1988); D, Lopez-Guisa et al (1988), E, Salomonsson et al (1984); F, Shinnick et al (1988).
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Hull													
Selma, unprocessed	67	Tr	Tr	Tr	33	NA	52	39	6	Tr	3	NA	B
Processed[g]	61	16	14	0	9	ND	45	49	4	0	2	ND	C
Bleached	8	77	14	0	1	ND	49	45	6	0	Tr	ND	C

[a]Glc = glucose, Xyl = xylose, Ara = arabinose, Man = mannose; Gal = galactose, Rha = rhamnose.
[b]A, Cummings and Englyst (1987); B, Frølich and Nyman (1988); C, Lopez-Guisa et al (1988); D, Salomonsson et al (1984); E, Shinnick et al (1988).
[c]Not detected. Rha and Gal coelute by high-performance liquid chromatographic method used.
[d]Trace, concentration not specified.
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